

K980247

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Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	Gynex Instruments GYNEX Corporation
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Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

MAR 17 1998

1. Device Name:

Trade Name: *Gynex Iris Hook*
Gynex Angle Hook
Gynex Emmett Tenaculum

Common Name: Tissue hook, tenaculum

Classification Name: Tenaculum

2. Establishment Name & Registration Number:

Name: GYNEX Corporation

Number: 3032109

3. Classification:

§ 884.4530 Obstetric-gynecologic specialized manual instrument. (a) Identification. An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance. This type of device consists of the following: (1) An amniotome is an instrument used to rupture the fetal membranes. (2) A circumcision clamp is an instrument used to compress the • foreskin of the penis during circumcision of a male infant. (3) An umbilical clamp is an instrument used to compress the umbilical cord. (4) A uterine curette is an instrument used to scrape and remove material from the uterus. (5) A fixed-size cervical dilator is any of a series of bougies of various sizes used to dilate the cervical os by stretching the cervix. (6) A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus. (7) A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination. (8) A cervical cone knife is a cutting instrument used to excise and remove tissue from the cervix. (9) A gynecological cerclage needle is a looplike instrument used to suture the cervix. (10) A hook-type contraceptive intrauterine device (IUD) remover is an instrument used to remove an IUD from the uterus. (11) A gynecological fibroid screw is an instrument used to hold onto a fibroid. (12) A uterine sound is an instrument used to determine the depth of the uterus by inserting it into the uterine cavity. (13) A cytological cervical spatula is a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina. (14) A gynecological biopsy forceps is an instrument with two blades and handles used for gynecological biopsy procedures. (15) A uterine tenaculum is a hooklike instrument used to seize and hold the cervix or fundus. (16) An internal pelvimeter is an instrument used within the vagina to measure the diameter and capacity of the pelvis. (17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina. (18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina. (b) Classification. Class II (performance standards).

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Device Class: Class II

Classification Panel: Ob/Gyn Devices Panel

Product Code: 85HDC

4. Preamendments Device:

1. Emmett Tenaculum Hooks, V. Mueller, The Surgical Armamentarium, 1973.

5. Equivalent Legally Marketed Device(s):

1. Uterine Tenaculum, K890379 - Mfg. by Kenetic Medical Products, Inc.
2. Champion Cervical Hook, K891349 - Mfg. by Simpson/Basye, Inc.
3. Zinnanti Atraumatic Tenacula, K890133 - Mfg. by Zinnanti Surgical, Inc.

6. Device Description:

The **Gynex Iris and Angle Hooks & Emmett Tenaculums** are made of 302 instrument grade stainless steel. All are used in similar way, each being a hook-like device used to snare, grasp, hold and manipulate the cervix, fundus and adjacent soft tissue. The important difference between the styles is that the radius of the hook tip is much smaller in the "Iris" and "angle" hook types. The devices are slender tapered metal rods, knurled on the proximal end and formed into a fine arc (hook) on the distal or working end. The devices are used to snare, hold and manipulate cervical and intravaginal tissue. Overall length of the hook/tenaculums is approximately 250mm for each type. The diameter of the hook tips is approximately 3mm for the Iris/angle styles and 8mm for the Emmett tenaculum style hook.

7. Applicant Name & Address:

GYNEX Corporation
16700 NE 79th St., Suite 204
Redmond, WA 98052

8. Company Contact:

Mr. Steve Angelo, President
GYNEX Corporation
16700 NE 79th St., Suite 204
Redmond, WA 98052
425.882.1179 * 425.895.0115 - fax

9. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
1000 Burnett Av., Suite 450
Concord, CA 94520
510.356.2640 - 510.356.2654 - fax

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10. Comparison Table:

FEATURE	Gynex Iris/Angle Hook & Emmett Tenaculum	Emmett Tenaculum Uterine Tenaculum, Champion Cervical Hook & Zinnanti Atraumatic Tenacula	SE?
Indications for Use(s):	Snare, grasp, hold & manipulate cervical and intravaginal tissue	Snare, grasp, hold & manipulate cervical and intravaginal tissue	YES
Design:	Slender tapered metal rod	Slender tapered metal rod	Yes
Sterilization Method:	Steam Autoclave	Steam Autoclave	YES
Sizes:	3mm & 8mm tip diameter	3mm & 4mm tip diameter	YES
Material:	302 Stainless steel	302 Stainless Steel	YES
Country of Origin::	Germany	USA - Germany	YES
Manufacturer:	Gynex Corporation	Simpson/Basye, Kenetic Medical Products, Zinnanti Surgical	YES
Product Code:	84HDC	84HDC	Yes
K - Number:	Pending	Preamendment - K890379, K891349, K891033 respectively	YES

11. Voluntary Standards:

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, GYNEX Corporation. Standard Operating Procedures (SOP), vendor certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

12. Storage, Packaging & Sterilization Information:

The *Gynex Iris/Angle Hooks & Emmett Tenaculums* are supplied in "clean only" condition and must be cleaned and sterilized prior to each use.

All packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. Any shipping damaged instruments should be returned promptly. Product for use in the operating room must be processed, opened, inspected, handled and placed into use following accepted operating room sterile technique.

Remove all labels and packaging materials before cleaning and sterilization. Wash the *Gynex Iris/Angle Hooks & Emmett Tenaculums* thoroughly with hot water using a typical hospital grade surgical instrument detergent or soap. Ultrasonic cleaners may be employed. Cleaning, rinsing and sterilization must be performed in accordance with usual hospital practice before first or any subsequent use.

The recommended sterilization process for the instruments is steam autoclave sterilization. The recommended sterilization cycle is: saturated steam at 270° F for 30 minutes. This is the typical or usual steam sterilization cycle use for surgical instruments.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1998

Gynex Corporation
c/o Mr. David W. Schlerf
Buckman Company, Inc.
1000 Burnett Avenue, Suite 450
Concord, CA 94520

Re: K980247
Gynex Iris Hook, Gynex Angle Hook, and
Gynex Emmett Tenaculum
Dated: January 23, 1998
Received: January 23, 1998
Regulatory Class: II
21 CFR 884.4530/Procode: 85 HDC

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K.980247

Device Name(s):

1. *GYNEX Tenaculum*
2. *GYNEX Iris Hook*
3. *GYNEX Angle Hook*

Intended Use:

1. *GYNEX Tenaculum - Grasp/manipulate the cervix & soft tissue*
2. *GYNEX Iris Hook - Grasp/manipulate cervical tissue*
3. *GYNEX Angle Hook - Grasp/manipulate cervical tissue*

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Rathny
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K.980247

Prescription Use ☒

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional format 1-2-96)